UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/719,770 | 09/06/2001 | Lawrence Steinman | STEINMAN 1B | 5046 |

1444 7590 07/11/2003

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

| EXAMINER | |
|---|---|
| KIM, JENNIFER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 07/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/719,770 | STEINMAN, LAWRENCE | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8,15 and 16* is/are pending in the application.

4a) Of the above claim(s) *4-7,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-3, 8 and 15 and 16 drawn to a method of treating neurodegenerative disease by administering a transglutaminase inhibitor with the species of monodansyl cadaverine in Paper No.13 is acknowledged. The traversal is on the ground(s) that the lack of unity restriction is improper since the diseases as claimed share a special technical feature in the fact that they are all mediated by transglutaminase, therefore, all can be treated by a transglutaminase inhibitor. This is not found persuasive because each inventions of Groups I-III lack the same or corresponding special technical feature since they have different known etiology and have acquired known different treatment therapy e.g. insulin dependent diabetes mellitus are treated different than multiple sclerosis or Hungtington's Disease. Further, the species are deemed to lack unity of invention because they lack common core in the structure, moreover, each active agents to be utilized have different properties and different effects. Therefore lack of unity requirement of last Office Action is deemed proper and made FINAL. Claims 4-7 are withdrawn from consideration since they are non-elected invention.

Further restriction (lack of unity) is required since Applicant's elected Group I, claims 1-3, 8, 15 and 16 contains the inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The inventions to be elected are as follows:

A. Claims 1-3 and 8, drawn to a method of treating disease mediated by transglutaminase comprising administering a transglutaminase inhibitor;

B. Claims 15 and 16, drawn to a method for treating disease mediated by transglutaminase comprising introducing DNA.

The inventions listed as Groups A and B do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons: Group A is related to a method of treating neurodegenerative disease comprising administering a transgutaminase inhibitor (organic compound) while Group B is related to introducing DNA (protein). The active agents or compounds to be utilized lack common central core and have different physical and chemical properties. **During a telephone conversation with Mr. Allen Yun on July 2, 2003 a provisional election was made with traverse to prosecute the invention of Group A, claims 1-3 and 8 with species of monodansyl cadaverine.** Affirmation of this election must be made by applicant in replying to this Office action.

Accordingly, Claims 4-7, 15 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson (WO 98/04245) in view of Chen (WO 92/13530).

Ferguson teaches the inhibitor of transglutaminase (i.e. monodansylcadaverine) useful for the treatment of healing wounds. (abstract, page 1, 2nd paragraph, page 3, lines 17-21).

Ferguson does not teach the specific diseases set forth in claim 3 or the mechanism set forth in claim 2.

Chen teaches that transgluaminases place important role in physiological processes such as wound healing and neuronal degenerative disease (i.e. Alzheimer's disease) and the wound healing and the neuronal degenerative diseases can be treated by administration of transglutaminase inhibitors (title, page 2, lines 11-24, page 4, lines 14-16).

It would have been obvious to one of ordinary skill in the art to employ monodansylcadaverine in treatment of the neurodegenerative disease set forth in claim 3 because Ferguson teaches that momodansylcadaverine is useful for treatment of the disease caused by transgluamineases and because Chen teaches that neuronal degenerative disease is caused by transgluaminase. One would have been motivated to employ transglutaminase inhibitor (i.e.

monodansylcadaverine) in treatment of any neuronal degenerative disease to achieve the therapeutic benefit of transgluaminase inhibitors in treatment of neuronal degenerative disease. Absent any evidence to contrary, there would have been reasonable expectation of successfully treating a patient suffering from any neurological disorders since neurological disorders are caused by abnormal transgutaminease activity as taught by Chen. The mechanism set forth in claim 2 would be obviously achieved upon above employment because the active ingredient gives same pharmacological effect (treatment of a disease mediated by transglutaminase) does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

***Allowable Subject Matter***

Claims drawn to specific active agents of claim 8 with the specific diseases set forth in claim 3 would be favorably considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
July 8, 2003